

Remarks

Election/Restrictions

In paragraph 2 of the Office Action, the Office stated that claims 6-31, drawn to non-elected subject matter, were withdrawn, there being no allowable generic or linking claim. But pursuant to MPEP 803.02, the Office must search and examine the generic claims, including non-elected subject matter, up to the full scope permitted by the prior art, up to the full scope of the claims. Rejections under 35 USC § 112 do not alleviate the Office of this obligation. Only if there is rejection under 35 USC § 102 or 103 can the Office limit the examination to the elected subject matter of a generic claims. Accordingly, as the subject matter of claims 6-31 is encompassed within the generic claims and no prior art rejections have been made, the applicants respectfully submit that this subject matter must be searched and examined, too, pursuant to MPEP 803.02.

Rejections under 35 USC § 112, ¶ 1, enablement

The Office rejected claims 1-5 and 32-48 as lacking enablement for “solvates,” “polymorphs,” and “prodrugs.” Without acquiescing or prejudice to future prosecution of such subject matter and solely in an effort to expedite prosecution, the applicants have deleted terms from the claims.

The Office also rejected claims 46-48 for lacking enablement of:

- a. all diseases and conditions in which FXR activity is associated; and
- b. “prevention” of such diseases.

First, claim 46 is directed to a composition comprising a compound of the invention together with a pharmaceutical carrier or vehicle and is independent of a particular disease. For this reason this rejection should be withdrawn as to this claim.

Second, claim 47 has been canceled without acquiescence to a rejection or prejudice to future prosecution. Thus, the rejection as to this claim has been obviated.

Lastly, claim 48 has been amended to recite treating or ameliorating specific diseases, thus obviating this rejection.

Rejections under 35 USC § 112, ¶ 2, definiteness

In paragraph 6, the Office Action enumerates various rejections (a-u), to which the applicants respond:

In parts (a) and (o), claims 1 and 46, respectively, and those dependent thereon were rejected for lack of antecedent basis for the recitation of R³³ and R³⁴. The Applicants respectfully disagree. The definition of R³⁰ and R³¹, which precedes the definition of R³³ and R³⁴ can independently be, for example, -N(R³³)R³⁴, thereby providing antecedent basis for R³³ and R³⁴.

In part (b) and (p), claims 1 and 46, respectively, and those dependent thereon were rejected for the recitation of a period at the end of the definition of R⁴, R⁵, R⁶, and R⁷. The claims have herein been amended to replace the period with semicolon.

In parts (c), (h), and (q), claims 1, 34, and 46, respectively, and claims dependent thereon were rejected for lack of antecedent basis for “R¹⁵, R¹⁶” in the 10th line to the bottom of page 4” for claim 1, “7th line from the bottom of page 18” for claim 34, and “12th line from the bottom of page 25” for claim 46. The applicants are confused with regard to these locations referred to in the Office Action as the claims begin on page 106, and even were one to count the first page of the claims as page 1 the locations referred to in the Office Action do not relate to R¹⁵ or R¹⁶. Regardless, R¹⁵ and R¹⁶ appear for the first time in moieties within the definitions of R¹ and R² and are then defined later in the claim. So, the applicants respectfully submit that there is no antecedent basis problem with R¹⁵ and R¹⁶.

In parts (d), (i), and (r), claims 1, 34, and 46, respectively, and claims dependent thereon were rejected for lack of antecedent basis for R²¹ and R²², again referring to page and line numbers that the applicants believe do not relate to these moieties. Nevertheless, R²¹ and R²² appear for the first time in moieties within the definition of R⁴, R⁵, R⁶ and R⁷ and are then defined later in each of the claims. As such, the applicants respectfully submit that there is no antecedent basis problem with R²¹ and R²².

In parts (e), (j), and (s), claims 1, 34 and 46, respectively, and claims dependent thereon, were rejected for the recitation of “R¹-R^{24” (claims 1, 34, and 46) and “R³⁰-R^{36” (claims 1 and 46). While the applicants respectfully traverse, they have amended the claims to recited each of R¹ through R²⁴ and R³⁰ through R³⁶, thereby obviating this rejection. These amendments do not change the scope of the claims but merely rephrase the claims in an equivalent manner.}}

In parts (f), (k), and (t), claims 1, 34 and 46, respectively, and claims dependent thereon were rejected because it was alleged that the meaning of $-N^+(R^{77})_3$ in the definitions of Q¹ and Q² was unclear as there was no indication of a counterion. The applicants respectfully traverse. The applicants' invention resides, in part, in compounds having a positively charged tertiary amino group, regardless of the counterion. The applicants respectfully submit that the recitation of a counterion is not necessary to define the applicants' invention nor for one of ordinary skill in the art to understand the meaning of the claim and its scope. Consequently, the applicants respectfully request reconsideration and withdrawal of this rejection.

In part (g), claim 34-42, 44 were rejected because it was alleged that the meaning of "derivative" was vague and indefinite. The Applicants respectfully disagree and draw the attention of the examiner to page 11, line 3, through page 12, line 29, of the specification, where the term "derivative" is defined. Nevertheless, the applicants have amended claims 7 and 34 to replace "derivative" with "salts, esters, enol ethers, enol esters, acetals, ketals, orthoesters, hemiacetals, hemiketals, acids, and bases, thereof," as defined in the specification.

In part (l) claim 42 was rejected for lack of antecedent bases for the recitation of -C(O)OH in the definition of R¹. Claim 42 ultimately depends from claim 34 through claim 42's dependence on claim 41, which depends on claim 40, which depends on claim 39, which depends on claim 38, which depends on claim 37, which depends on claim 36, which depends on claim 35, which depends on claim 34. Claim 34 provides antecedent basis of R¹ = -C(O)OH through its definition of R¹ including -C(O)OR¹⁴ and the definition of R¹⁴ including hydrogen. The applicants have amended claims 42 so that it depends from claim 34, inserting the limitations of claim 40 and 41. Thus, the scope of claim 42 remains unchanged through this amendment while proper antecedent basis is provided for the recitation of R¹ = -C(O)OH.

In part (m), claim 42 was rejected for lack of antecedent basis for the recitation of R¹ is -C(O)N(CH₃)(cyclopropyl). The amendment made to claim 42 discussed in the previous paragraph address this issue as well as claim 36 provides antecedent support for R¹ = -C(O)N(CH₃)(cyclopropyl).

In part (n), claim 45 was rejected for lack of antecedent basis for the recitation of "1,2,3,4,5,6,7,8,9,10-decahydrozpino[4,5-b]indole." This compound has been deleted from the claim, thereby obviating this rejection.

In part (u), claim 47 was rejected because it was alleged that the scope of the claim was indefinite in terms of which diseases were encompassed. While the applicants respectfully traverse, the rejection has been obviated by cancellation of claim 47.

Claim Objections

Claims 3-5, 32, and 33 were rejected as being in improper multiple dependent form. Claim 3 has been amended to delete reference to claim 1 as being unnecessary, claim 3 ultimately depending from claim 1 through its dependence on claim 2. (Similarly, claim 2 was amended to delete reference to claim 1 as being unnecessary.)

The applicants respectfully submit that the foregoing arguments and amendments overcome all pending rejections, and, furthermore, pursuant to MPEP 803.02 the applicants are entitled to a search of the full scope of the claims permitted by the prior art (irrespective of any issues under 35 USC § 112). If art is found rendering the claims unpatentable under 35 USC § 102 or 103, the next Office Action cannot be made final because the applicants were entitled to such a search before the first Office Action.

If it is believed that a teleconference will advance prosecution, the examiner is encouraged to contact the undersigned as indicated below.

Respectfully submitted,

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